

REMARKS

Claims 1 and 3-9 are pending in the present application. Claims 1, 3, 4 and 6-9 are rejected. Claims 1, 5, 6 and 9 are herein amended. New claims 10-13 are herein added. No new matter has been added.

Unity

The Office Action maintains that there is a lack of unity between Group I (claims 1, 3, 4 and 6-9) and Group II (claim 5). The Office Action alleges that these claims do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The Office Action identifies the technical feature of Group I as a protein complex and the technical feature of Group II as a method for producing a protein complex.

In response, Applicant respectfully submits that Group I and Group II share a general inventive concept which is a contribution over the prior art. Specifically, Groups I and II share at least the inventive concept of a target protein fused to a restricted region of a VP3 protein. Thus, Applicant respectfully submits that claim 5 should be considered in accordance with PCT Rule 13.2. Favorable reconsideration is respectfully requested.

Applicant's Response to Claim Rejections under 35 U.S.C. §112

Claims 1, 3, 4 and 6-9 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 3, 4 and 6-9 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

The Office Action maintains these arguments from the previous Office Action, and provides essentially the same comments. These rejections are mainly based on the fact that the claims generally recite a VP3 protein of a cytoplasmic polyhedrosis virus (CPV), while the specification gives a single specific example of a VP3 protein of a CPV. Specifically, the Example in the specification deals with the VP3 protein of strain H of the *Bombyx mori* CPV.

In response, Applicant herein amends the claims to recite the VP3 protein of strain H of BmCPV. Applicant respectfully submits that this subject matter is fully described and enabled by the specification. Favorable reconsideration is respectfully requested.

Applicant's Response to Claim Rejections – Double Patenting

Claims 1, 3, 4, and 6-9 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 18 of co-pending U.S. Patent Application No. 10/415,096, which corresponds to Ohta et al. (WO 02/36785) as cited below.

In response, Applicant respectfully submits that the claims of the pending application are patentably distinct over Ohta, for at least the reasons discussed below. Specifically, Applicant respectfully submits that Ohta discloses fusing a target protein to a complete VP3 protein, and does not disclose fusing a target protein to a restricted region of VP3 from the 41st to 79 residues.

As such, the pending claims are patentably distinct over Ohta. Favorable reconsideration is respectfully requested.

Applicant's Response to Claim Rejections under 35 U.S.C. §102/103

Claims 1, 3 and 4 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over, Ohta et al. (WO 02/36785).

It is the position of the Office Action that Ohta discloses the invention as claimed. The Office Action appears to recognize that the pending claims are intended to recite a target protein and residues 41-79 of a VP3 protein. However, the Office Action broadly interprets the phrase "a target protein *having* a restricted region" as being synonymous with "comprising." Thus, the Office Action interprets Ohta as disclosing the embodiment as claimed. In other words, the Office Action interprets Ohta's disclosure of a target protein fused to a complete VP3 protein as disclosing the claimed embodiments, since a complete VP3 protein is a protein *having* residues 41-79.

In response, Applicant herein amends the claims to recite a target protein fused to a restricted region. This amendment is supported at least by page 4, lines 7-10, where it is stated that "the amino acid sequence of VP3, which is a constituent protein of the envelope of cytoplasmic polyhedrosis virus, is introduced to the N-terminus or the C-terminus of the target protein, and this fusion protein is expressed with a baculovirus vector." Applicant respectfully submits that Ohta discloses fusing a target protein to a complete VP3 protein, and does not

disclose fusing a target protein to a restricted region of VP3 from the 41st to 79th residues.

Favorable reconsideration is respectfully requested.

Applicant's Response to Claim Rejections under 35 U.S.C. §103

Claim 6 was rejected under 35 U.S.C. §103(a) as obvious over Ohta in view of Hosokawa et al. (Materials Research Society, Symposium C, Bio-Inspired Nanoscale Hybrid Systems, December 2002, Abstract C3.5) and Ito et al (Appl. Physics Lett. 78: 2566-2568, 2001).

It is the position of the Office Action that Ohta discloses the invention as claimed, with the exception of teaching the biosensor. The Office Action relies on Hosokawa and Ito to provide this teaching.

In response, Applicant respectfully submits that the disclosures of Hosokawa and Ito do not remedy the deficiencies of Ohta discussed above. For at least this reason, Applicant respectfully submits that claim 6 is patentable over the combination of Ohta, Hosokawa and Ito. Favorable reconsideration is respectfully requested.

Claims 7-9 were rejected under 35 U.S.C. §103(a) as obvious over Ohta.

It is the position of the Office Action that Ohta discloses the invention as claim. In response, Applicant respectfully submits that claims 7 and 8 are patentable at least due to their dependency on claim 1, which Applicant submits is patentable for at least the above reasons. As

to claim 9, Applicant respectfully submits that this claim is patentable at least due to similar reasons as to claim 1, above. Favorable reconsideration is respectfully requested.

Applicants' Additional Comments in Response to Remarks in the Advisory Action

In the Advisory Action, it was acknowledged that the proposed amendments recited a target protein "fused to" a restricted region. The Advisory Action indicated this may be read in one of two ways: (1) a target protein is directly fused to a restricted region, or (2) a target protein is fused indirectly to a restricted region via a "linker," and the "linker" in such an indirect fusion may be sequences 1-40 of BmCPV.

Interpretation (1) is illustrated below:

"Target protein"	"restricted region"
-----	=====
	(41) VP3 strain H BmCPV (79)

Interpretation (2) is illustrated below:

"Target protein"	"linker"	"restricted region"
-----	+++++	=====
	(1) VP3 strain H BmCPV	(40)(41) VP3 strain H BmCPV (79)

With respect to interpretation (2) above, Applicants respectfully submit that where amino acids 41-79 of the VP3 of strain H of BmCPV are contiguous with amino acids 1-40 of the VP3 of strain H of BmCPV, the sequence of amino acids 41-79 of the VP3 of strain H of BmCPV cannot be considered "a restricted region." The recitation of a "restricted region" (as opposed to "a region") requires that the restricted region has been excised from the full protein. In other

words, the “restricted region” requires that amino acids 40 and 41 of the VP3 of strain H of BmCPV have been “cut” from each other. In other words, while the Office may broadly interpret the term “fused to” to include indirect fusion, the term “a restriction region” cannot be reasonably interpreted to include a non-restricted region.

However, in view of the comments in the Advisory Action, Applicants herein add new dependent claims which specify that the fusion is a direct fusion. Please see new claims 10-13. Independent claims 1, 5, 6 and 9 may be interpreted to encompass the following subject matter (A) and (B), below:

(A)

“Target protein”	“restricted region”
-----	=====
	(41) VP3 strain H BmCPV (79)

(B)

“Target protein”	“linker”	“restricted region”
-----	+++++	=====
	(any appropriate linker)	(41) VP3 strain H BmCPV (79)

Meanwhile, new dependent claims 10-13 only encompass the following subject matter:

“Target protein”	“restricted region”
-----	=====
	(41) VP3 strain H BmCPV (79)

Applicants respectfully submit that independent claims 1, 5, 6 and 9, as well as dependent claims 10-13 are patentable over the cited art. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.


Application No.: 10/541,752
Art Unit: 1656

Amendment under 37 CFR 1.114
Attorney Docket No.: 052777

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp